



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Developing an Evidentiary Standards Framework for Safety Biomarkers Qualification; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), in co-sponsorship with the Foundation for the National Institutes of Health Biomarkers Consortium (FNIH BC), is announcing a public workshop entitled “Developing an Evidentiary Standards Framework for Safety Biomarkers Qualification Workshop.” The purpose of the workshop is to discuss the evidentiary standards needed to support biomarker qualification with a particular emphasis on drug safety markers. The 2-day workshop will focus on the standards relevant to the qualification of a range of safety biomarkers and examine case studies in several different organ systems.

DATES: The public workshop will be held on April 14, 2016, from 9 a.m. to 5 p.m. and April 15, 2016, from 8 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at the Bethesda North Marriott Hotel and Conference Center, 5701 Marinelli Rd., Bethesda, MD 20852.

FOR FURTHER INFORMATION CONTACT: Janelle Lewis, Foundation for the National Institutes of Health, 9650 Rockville Pike, Bethesda, MD 20814, 301-594-2919, FAX: 301-480-2752, email: [jlewis@fnihi.org](mailto:jlewis@fnihi.org).

SUPPLEMENTARY INFORMATION: The need for evidentiary standards to qualify biomarkers was identified in FDA's Critical Path Initiative as essential to improving the efficiency and effectiveness of drug development. Evidentiary standards vary among different types of biomarkers and according to the context(s) of use (COU) for which qualification is being considered, and there are specific challenges involved in qualifying drug safety biomarkers. This workshop is aimed at creating alignment among scientific stakeholders including FDA, the National Institutes of Health (NIH), the biopharmaceutical industry, academic researchers, and patient groups regarding a proposed framework for determining the levels of evidence required to qualify biomarkers for use in drug development, with an emphasis on biomarkers used in determinations of drug safety assessments. Development of a general framework for biomarker qualification will be discussed, along with specific application to different COUs related to drug safety, including consideration of several specific case studies involving qualification of clinical markers of toxicity in different organ systems.

Registration: There is no fee to attend the workshop, but attendees must register in advance. Space is limited, and registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online at [www.fnih.org/evidentiarystandardsworkshop](http://www.fnih.org/evidentiarystandardsworkshop) by April 1, 2016. For those persons without Internet access, please contact Janelle Lewis at the Foundation for the NIH (see FOR FURTHER INFORMATION CONTACT) to register.

Attendees are responsible for their own hotel accommodations. Attendees making reservations at the Bethesda North Marriott Hotel and Conference Center (see ADDRESSES) are eligible for a reduced rate of \$226 per night (equivalent to the government per diem rate), not

including applicable taxes. To receive the reduced rate, follow the Web link that will be provided to you upon completion of online registration.

If you need special accommodations due to a disability, please contact Janelle Lewis (see FOR FURTHER INFORMATION CONTACT) at the Foundation for the NIH at least 7 days in advance of the workshop.

Dated: February 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-04027 Filed: 2/24/2016 8:45 am; Publication Date: 2/25/2016]